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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,933	03/01/2001	Elisabeth Henriette Burger	702-002201	8311

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EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,933

Applicant(s)

BURGER ET AL

Examiner

Thomas S. Heard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 8, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35 and 64-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35 and 64-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>May 04, 2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

The amendment filed August 8, 2005 is acknowledged and has been entered. Claims 35-68 are currently pending in this application. Claims 35, 64, and 66 have been amended. Claims 36-63 have been canceled. The text of those sections of Title 35, U.C. Code not included in this action can be found in the prior Office Action.

Double Patenting

Applicant's arguments filed August 8, 2005 have been fully considered but they are not persuasive. Applicant's have argued that the obviousness-type double patenting does not apply because the instant application has an earlier priority date that 10/627,314. The fact of an earlier priority date does not eliminate the fact that if both patents were to issue, the Applicant's would be in possession of two patents that are obvious over one another. However, Applicants are advised that should the instant application be put into condition for allowance before 10/627,314, then this provisional obviousness-type double patenting will be withdrawn.

New Obviousness-Type Double Patent Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35, 64-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 6,638,531 in view of Helmerhorst et al, "Synthetic Histatin Analogues with Broad-spectrum Antimicrobial Activity," Biochem J, Vol. 326, 39-45 (1997), presented in the previous office action. The instantly claimed in invention is drawn to pharmaceutical compositions and methods of use comprising the peptide LLLFLLKKRKKRKY (SEQ ID NO: 9) and bone material is a pharmaceutical composition that is capable of containing antimicrobial peptides. Hamanishi et al teaches a "tetracalcium phosphate-dicalcium phosphate dihydrate (UCP-DCPD) apatite cement" (bone material) that hardens into a hydroxyapatite phase that is similar to bone and incorporates (includes) Vancomycin for the treatment of osteomyelitis. Hamanishi teaches that the UCP-DCPD cement can accommodate many drugs without denaturation (if a peptide drug), see page 139 and first paragraph, and page 142 and second column. Hamanishi further teaches the method of mixing the cement powder in a liquid medium in combination with Vancomycin and allowing the bone cement mixture to set. In vivo data is provide in support of the release of the antibiotic and osteomyelitis treatment.

Claim Rejections - 35 USC § 112

Applicant's arguments, see page 4 and 4th paragraph, filed August 8, 2004, with respect to 112 second paragraph have been fully considered and are persuasive. The rejection of 35-68 has been withdrawn.

Applicant's arguments, see page 4 and 5th paragraph, filed August 8, 2004, with respect to 112 1st rejection have been fully considered and are persuasive. The rejection of 35-41, 50-56, and 58-64 has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments, see page 5 at line 11, filed August 8, 2005, with respect to 103(a) rejection have been fully considered and are persuasive. The rejection of claims 35-68 has been withdrawn.

Conclusion

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TSH

A handwritten signature in black ink that reads "Bruce Campell". The signature is written in a cursive, flowing style.

**BRUCE R. CAMPPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**